DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Preservation Solutions, Inc.
John R. Dalpee
Regulatory Affairs
P. O. Box 937
Elkhorn, WI 53121

JUL 27 2015

Re: K022826
Trade/Device Name: Clear-It Anti-Fog Solution
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: OCT
Dated (Date on orig SE ltr): August 19, 2002
Received (Date on orig SE ltr): August 26, 2002

Dear Mr. Dalpee,

This letter corrects our substantially equivalent letter of October 9, 2002.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

PSI *Preservation Solutions, Inc.*

Ph. (262) 723-6715
Fax (262) 723-4013
P.O. Box 937
Elkhorn, WI 53121-0937

510(k) Number: K022826

Device Name: Clear-It Anti-Fog Solution

Indications For Use:

Clear-It Anti-Fog Solution is indicated for use in the sterile surgical arena to eliminate condensation from endoscopic lenses, microscope lenses, goggles and other devices that are likely to fog.

Please do not write below this line. Continue on another page if needed

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over-The-Counter Use ____
21CFR 801.109

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K022826

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510(k) Premarket Notification Information

Applicant:	Preservation Solutions Inc. P.O. Box 937 Elkhorn WI. 53121
Device Name	Clear-It® Anti-Fog Solution
Registration Number:	Preservation Solutions Inc. Establishment Registration Number is 2132588
Classification:	Class II, 21 CFR Part 876.1500, Endoscope and/or Accessories.
Product Code:	KOG
Panel:	Gastroenterology
Device Description:	Clear-It Anti-Fog is a solution whose primary ingredients are Water, Isopropyl Alcohol, Sodium Alcohol Ether Sulfate, and Ammonium Dodecylbenzene proportionally mixed balanced and packaged according to approved manufacturing processes. Clear-It Anti-Fog is terminally sterilized by gamma irradiation. The appropriate dose was established using ISO 11137 method I protocol. Quarterly dose audits are performed using the same ISO 11137 protocol. Routine production testing prior to release includes pH, cytotoxicity, efficacy, and bacterial endotoxin.
Labeling:	Labeling for this device is contained in Appendix A